



08-04-05

1646

PATENT

Attorney Docket No. 01736349

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

9/16/03

In re Application of: )  
Robert E. DUDLEY ) Group Art Unit: 1646  
Application No. 09/703,753 ) Examiner: Jiang, S.  
Filed: November 1, 2000 )  
For: METHOD FOR TREATING )  
ERECTILE DYSFUNCTION )  
AND INCREASING LIBIDO )  
IN MEN )

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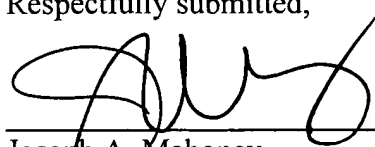
Dear Sir:

Enclosed herewith are the following for the above-captioned application:

1. Supplemental Information Disclosure Statement;
2. PTO Forms SB/08A and SB/08B;
3. Copies of cited references;
4. Check in the amount of \$180.00 for Supplemental Information Disclosure Statement fee; and
5. Return receipt postcard.

The Commissioner is hereby authorized to charge any additional filing fees required under Rule 1.17 concerning this transaction, or to credit any overpayment to Deposit Account 13-0019.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Mahoney', is written over a horizontal line.

Joseph A. Mahoney

Reg. No. 38,956

Date: August 1, 2003

**MAYER, BROWN, ROWE & MAW LLP**

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Chicago, Illinois 60690-2828

Telephone: (312) 701-8979

Facsimile: (312) 706-9000



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37**  
**C.F.R. § 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents listed on the attached PTO/SB/08A and PTO/SB/08B documents. Copies of the listed documents are enclosed.

This Supplemental Information Disclosure Statement is being submitted after the mailing date of the first Office Action on the merits. A check in the amount of \$180.00 is enclosed.

Applicant respectfully requests that the Examiner consider the listed documents and evidence that consideration of relevant portions thereof by making appropriate notations on the attached form.

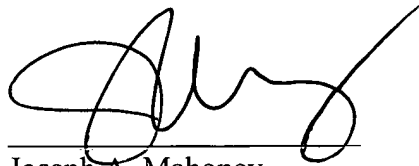
This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each of all of the listed documents are material or constitute "prior art." If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

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01 FC:1806

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee in connection with the filing of this statement, please charge the fee to our Deposit Account No. 13-0019.

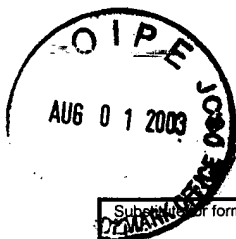
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Joseph A. Mahoney  
Reg. No. 38,956

Dated: August 1, 2003

**MAYER, BROWN, ROWE & MAW LLP**  
P.O. BOX 2828  
CHICAGO, ILLINOIS 60690-2828  
(312) 701-8979



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/703,753
				Filing Date	November 1, 2000
				First Named Inventor	DUDLEY, Robert E.
				Art Unit	1646
				Examiner Name	JIANG, S.
Sheet	1	of	1	Attorney Docket Number	01736349

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1	4,663,157	05-05-87	Brock, E.D.	
	2	4,699,779	10-13-87	Palinczar, V.	
	3	5,023,252	06-11-91	Hsieh, D.	
	4	5,446,025	08-29-95	Lu, M.F.	
	5	5,731,303	03-24-98	Hsieh, D.	
	6	5,891,462	04-06-99	Carrara, D.	
	7	6,503,894	01-07-03	Dudley, R.E.	

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	8	AU 4998490	09-20-90	Amway Corp.		
	9	AU 9141391	06-25-92	Theratech Inc.		
	10	EP 189861	08-06-86	Showa Denko		
	11	EP 332147	09-13-89	Warner-Lambert		
	12	EP 552405	11-25-98	Lintec Corp.		
	13	EP 811381	05-02-03	Permotech N.V.		
	14	GB 1158283	07-16-69	Foster-Milburn		
	15	JP 62-011675	08-02-94	TEZUKA		
	16	WO 87/03473	06-18-87	Hsieh, D.		
	17	WO 92/07586	05-14-92	Beecham Group PLC		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Form for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

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Filing Date	November 1, 2000
First Named Inventor	DUDLEY, Robert E.
Art Unit	1646
Examiner Name	JIANG, S.
Attorney Docket Number	01736349

Sheet 1 of 1

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**NON PATENT LITERATURE**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS); title of the article (when appropriate); title of the item (book, magazine, journal, serial symposium, catalog, etc.); date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	DELANOE et al., "Androgenisation of Female Partners of Men on Medroxyprogesterone Acetate/Percutaneous Testosterone Contraception," The Lancet (Feb 1984), p. 276.	
	2	DEMERY, A. "Contraception Masculine" Soins Gyn.-Obs.-Puer.-Ped., No. 72 (May 1987) pp. 33-38.	
	3	MARBURY et al., "Evaluation of the Pharmacokinetic Profiles of the New Testosterone Topical Gel Formulation, Testim(TM), Compared to AndroGel(R)," Biopharm. Drug Dispos., 24:115-120 (2003).	
	4	MORGAN et al., "Enhanced Skin Permeation of Sex Hormones with Novel Topical Spray Vehicles," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1213-1218.	
	5	MORGAN et al., "Enhanced Transdermal Delivery of Sex Hormones in Swine with a Novel Topical Aerosol," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1219-1225.	
	6	POPE JR., et al., "Testosterone Gel Supplementation for Men with Refractory Depression: A Randomized, Placebo-Controlled Trial," Am. J. Psychiatry, 160(1): 105-111 (2003).	
	7	SCHOOR, M., "Livening Up Libidos: Testosterone Patches Can Help Revive Women's Sex Drive," www.abcnews.com, September 6, 2000.	
	8	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1998, filed on March 22, 1999.	
	9	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1999, filed on March 14, 2000.	
	10	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1996, filed on March 28, 1997.	
	11	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1997, filed on March 31, 1998.	
	12	CELLEGY PHARMACEUTICALS, INC.: INVESTORS: PRESS RELEASES, "Cellegy Pharmaceuticals Receives FDA Nonapproval Letter for Fortigel," July 7, 2003, www.cellegy.com.	
	13	PERCUTACRINE STRONG ANDROGENIC Testosterone Percutacrine Androgenique Forte from VIDAL dictionary (1985).	X
	14	Protest Under 37 CFR 1.291(a) of U.S. Patent Application No. 09/651,777 dated August 20, 2002.	

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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.